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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/529,128	06/30/2000	GRAHAM FRANCOIS DUIRS	08059-0001	2910

22852 7590 07/16/2007  
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WASHINGTON, DC 20001-4413

EXAMINER
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GILBERT, ANDREW M

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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07/16/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

09/529,128

Applicant(s)

DUIRS, GRAHAM FRANCOIS

Examiner

Andrew M. Gilbert

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-14 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-14 and 17-20 is/are rejected.
- 7) ☒ Claim(s) 7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Acknowledgments***

1. This office action is in response to the reply filed on 5/21/2007.
2. In the reply, the applicant amended claims 1, 8 and added new claim 20.
3. Additionally, the applicant filed a Terminal Disclaimer that has been APPROVED to obviate the rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6770288.
4. Thus, claims 1-9, 11-14, 17-20 are pending for examination.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-6, 8-9, 12-14, 17-19 rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al (5816248). Anderson et al discloses an internal substance delivery device for insertion into a body cavity (Abstract), the device includes a support frame (38) having at least two resilient arms (48, 58) which retain the device in the body cavity, wherein each resilient arm is capable of receiving and releasing a separate pod (54, 64) capable of releasing a drug contained within a matrix of the pod into the body cavity (Abstract, col 3, Ins 52-67; col 4, Ins 18-col 5, Ins 37, especially col

5, Ins 30-37 and col 10, Ins 38-44), and wherein the at least two resilient arms are biased outward from a central section (Fig 3) of the support frame; wherein the substance is a drug (Abstract, col 3, Ins 52-67; col 4, Ins 18-col 5, Ins 37); wherein the device is an intra-vaginal release device (Abstract, col 3, Ins 52-67; col 4, Ins 18-col 5, Ins 37); wherein the substance is released from the pod through osmosis (col 3, Ins 52; col 4, Ins 18-32, col 5, Ins 18-37; col 10, Ins 37-44) wherein the pod is rounded (Fig 3; 54, 64); wherein at least one of the pods is flexibly attached to a corresponding arm (Fig 3; Abstract, col 3, Ins 52-67; col 4, Ins 18-col 5, Ins 37); wherein the support frame is in the form of a wish bone (Fig 3); wherein the at least two resilient arms are sufficiently pliable to be moved together to allow the substance delivery device to be effectively compressed (Abstract, col 3, Ins 52-67; col 4, Ins 18-col 5, Ins 37); wherein the at least two resilient arms are capable of interlocking for removal or insertion (Abstract, col 3, Ins 52-67; col 4, Ins 18-col 5, Ins 37); wherein the support frame includes a locator (68; Abstract, col 3, Ins 52-67; col 4, Ins 18-col 5, Ins 37) to enable the substance delivery device to be readily located and removed from in situ. The Examiner strongly recommends structurally defining the Applicant's pod structure (additionally, see discussion below in Response to Arguments).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. Anderson et al discloses the invention substantially as claimed except for expressly disclose the support frame being made out of nylon. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the support frame out of nylon because the Applicant has not disclosed that making the support frame out of nylon provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the support frame material of Anderson et al because the material performs substantially the same function in substantially the same manner. Therefore, it would have been an obvious matter of design choice to modify Anderson et al to obtain the invention as specified in claim 11.

9. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. Anderson et al discloses the invention substantially as claimed except for expressly disclosing that the matrix is a cellulose matrix. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the matrix be of cellulose because the Applicant has not disclosed that having the matrix be specifically made of cellulose provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the matrix (col 5, lns 34-37; col 10, lns 38-44) of Anderson et al because the matrix performs substantially the same function in substantially the same

manner. Therefore, it would have been an obvious matter of design choice to modify Anderson et al to obtain the invention as specified in claim 20.

***Response to Arguments***

10. Applicant's arguments filed 5/21/2007 have been fully considered but they are not persuasive.

11. The Applicant argues that Anderson et al does not disclose a substance delivery device including a pod capable of releasing a drug contained in a matrix of the pod into a body cavity (Remarks, pg 10, paragraph 4).

12. The Examiner respectfully disagrees and notes that Anderson et al explicitly discloses a pod (54, 64) capable of releasing a drug (col 3, lns 56-67) contained within a matrix (col 5, lns 27-37; col 10, lns 38-44) of the pod into a body cavity. The Examiner notes that this delivery may be performed in a plurality of manners, including natural passive delivery, such as osmosis, or by an active delivery mechanism such as iontophoresis or phonophoresis. Thus, Anderson explicitly discloses the Applicant's claim limitations. The Examiner suggests further structurally defining the Applicant's pod structure and the connection between the pod and the support frame to further distinguish the Applicant's invention.

***Allowable Subject Matter***

13. Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew Gilbert

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

